K081062

Airsonett

510(k) Summary

NOV - 7 2008

Submitter:
Airsonett Inc
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Fort Mill, SC 29708

Contact Information:
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Submission Date:
April 9, 2008

Proprietary Name:
Airsonett Airshower Air 3 Mobile Medical Air Cleaner

Device Name and Classification:
Sec. 880.5045 Medical Recirculating Air Cleaner.

Equivalent Device Identification:
BREATHE EASY (Models AD and CD) by RespirAid Ltd (K981841)

Device Description:
The Airsonett Airshower Air 3 Mobile Medical Air Cleaner is an adjustable, portable, personal system for use in providing a controlled environment for medical applications that require a high degree of airborne particulate control. The system is controlled by embedded firmware and runs on standard 115 volt, 1.7 ampere power. Pushbutton controls include airflow and cooling capacity. Manual controls include tilt/angle of air outflow.

The Airsonett Airshower Air 3 Mobile Medical Air Cleaner device provides a method, using air cooling, for guiding the treated ambient air so as to obtain an air flow distribution directly to the users breathing zone, thereby forming a treated air zone surrounding the user.

The Airsonett Airshower Air 3 Mobile Medical Air Cleaner has been designed to meet the following product safety standards:

- IEC 60601-1 - Standard for Medical Electrical Equipment - Part 1 : General Requirements for safety (IEC 601-1:1988)

Intended Use

The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Comparison Table:

Element of Comparison	**Subject Device**	**Claimed SE Device**
	Airsonett AB	RespirAid Ltd.
Type of Medical Re-circulating Air Cleaner	Mobile Air Filtration system	Mobile Air Filtration system
Intended use	The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.	The BREATHE EASY device is a medical recirculating air cleaner designed to remove airborne particles and allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites and harmful fibers, that may lead to allergic reactions.
Type of device	Over the counter use	Over the counter use
Labeling	**Airsonett Airshower Air-3**	**BREATHE EASY**
Product Description	Housing Unit	Housing Unit
	Air Inlet and Treated Air Outlet	Air Inlet and Treated Air Outlet
	Blower	Blower
	HEPA filter	HEPA filter
	Air Warming Unit	Air Warming Unit
	Air Cooling Unit	-
	-	Humidifier
	Adjustable Air Guidance Arm	Adjustable Support Arm
	Control Panel	-

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Element of Comparison	Subject Device	Claimed SE Device
	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.	The Breathe Easy uses a flow guide to isolate the respiratory passages of a user from ambient air. Method for guiding the treated air outflow so as to obtain a flow distribution in close proximity to the head of the user, thereby forming a treated air envelope surrounding his respiratory openings.
Power Requirements	115 Volts (60Hz), 1.7 Amps	115 Volts
Standard	IEC 60601-1	IEC 601-1
Air Flow	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h	20-40 m^3/h
Air Quality in treated air envelope (referred as clean zone in appendix 1.7)	Class 100-1000 according to FED STD 209E	Class 100-1000 according to FED STD 209E
Rate of Air Changed	~1500 changes per hour	400-600 changes per hour
Sound Level	~38 dB(A)	Maximum 50 dBA or less

Summary of Testing: The device was tested for filter functionality and efficiency. Software functions were verified and validated. The device was EMC and safety tested according to relevant standards. The device functioned according to specifications.

Conclusion: Airsonett Airshower Air-3 is substantially equivalent to Breathe Easy regarding technology, intended use and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Airsonett, Incorporated
C/O Ms. Constance G. Bundy
C.G. Bundy Associates, Incorporated
6470 Riverview Terrace
Findley, Minnesota 55432

NOV - 7 2008

Re: K081062
Trade/Device Name: Airsonett Airshower Air 3
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: October 13, 2008
Received: October 21, 2008

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anette Y. Michaud MD
FOR DR. CHIU LIN

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K081062**

Device Name: **Airsonett Airshower Air 3**

Indications For Use:

The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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